

SFHCHS203

Validate equipment, medical devices, products and associated systems within healthcare



Overview

This standard relates to the application of validation tests that are applied whenever a new methodology or technique is introduced and for any new equipment, medical device, product and their associated systems.

This standard covers a wide range of validation tests used for equipment, products, devices and their associated systems.

It may be performed by the manufacturer or specialist health staff. Individuals undertaking this function will liaise closely with relevant stakeholders to confirm accuracy of information and compliance with relevant legislation.

Users of this standard will need to ensure that practice reflects up to date information and policies.

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Performance criteria

You must be able to:

- P1 work within your level of competence, responsibility and accountability
- P2 apply appropriate health and safety measures, infection prevention and control and personal protective equipment within the validation process
- P3 perform the validation through sufficient testing using approved test protocols and procedures in line with current legislation and organisational requirements
- P4 check all results against defined standards in accordance with local and national protocols, standards and guidelines
- P5 assess the suitability of the equipment, device, product and associated systems under test for its intended purpose
- P6 liaise with relevant stakeholders on the findings of the validation process
- P7 report results in acceptable format, recording compliance and any variances or non-compliances at the required level of detail for the target audience
- P8 identify with key individuals any recommendations for action to ensure effective performance of equipment, devices, products and associated systems
- P9 maintain full, accurate and legible records of information and store in correct location in line with current legislation, guidelines, local policies and protocols

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Knowledge and understanding

You need to know and understand:

- K1 your own level of competence, authority and specialist knowledge base
- K2 the key principles and relevant scientific and/or technical data associated with the validation test
- K3 where to obtain technical or specialist advice and support
- K4 how to liaise with key stakeholders to review options and select most suitable validation tests
- K5 how to liaise and consult with key stakeholders to produce new techniques based on proven principles and practice, if no suitable validation tests exists
- K6 the capabilities and limitations of equipment, devices, products and associated systems undergoing validation
- K7 the clinical setting, intended purpose and expected performance parameters of equipment, medical devices and associated systems
- K8 the range of health and safety measures, infection prevention and control and personal protective equipment, their importance and application within validation
- K9 principles of risk assessment applied to validation methods for new equipment, devices, products or techniques within your work practice
- K10 the range and operational details of the associated utility requirements for the specific equipment, device or product
- K11 the importance of and how to check the functionality of any existing or new utility requirements for the equipment, device or product under test and where to seek advice is this is outside your competence and level of responsibility
- K12 the importance of and how to review and select the protocols for the validation process
- K13 the protocols and procedures for dealing with non-conformance, variances or failure and the actions required
- K14 the importance of maintaining records of validation tests and how to store in the correct location to enable retrieval
- K15 the importance of and the requirements for signing off handover documentation
- K16 the current national legislation, guidelines, local policies and protocols which affect your work practice
- K17 the policies and guidance that clarify your scope of practice, accountabilities and the working relationship between yourself and others

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Additional Information

External Links

This standard links with the following dimension within the NHS Knowledge and Skills Framework (October 2004):

Dimension: G2 Development and innovation

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Developed by Skills for Health

Version number 1

Date approved June 2010

Indicative review date June 2012

Validity Current

Status Original

Originating organisation Skills for Health

Original URN CHS 203

Relevant occupations Health, Public Services and Care; Nursing and Subjects and Vocations Allied; Health Professionals; Healthcare and Related Personal Services

Suite Clinical Health Skills

Key words adapt, assistive technology, rehabilitation, calibrate
